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### 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is : K964215

This summary was prepared on December 16, 1996

#### A. Submitter

Smith & Nephew Endoscopy  
130 Forbes Boulevard  
Mansfield, MA 02048

Establishment Registration Number: 1219602

#### B. Company Contact

Tedd Gosian  
Clinical / Regulatory Manager

#### C. Device Name

Trade Name:	Acufex® MosaicPlasty™ Comprehensive System
Common Name:	Drill Bits, Chisels, Trephines, Tamps, Drill Guide, Compression Instrument
Classification Name:	Orthopedic Manual Surgical Instruments, Template Surgical Instruments Motors Accessories

#### D. Predicate/Legally Marketed Devices

All of the components in the MosaicPlasty Comprehensive System are Class I Exempt Devices, except drill bits and adapters which are Class I.

Predicate/Legally Marketed Devices include:

Drill Guide	Synthes®
Drill Bits	Synthes®
Gouges	Synthes®
Trephine Drills	Smith & Nephew Endoscopy
Tamps	Zimmer®
Bone Grafters	Instrument Makar®
Bone Compression Forceps	KMedic®

#### **E. Device Description**

The MosaicPlasty Comprehensive System is a kit composed of several orthopedic manual surgical instruments. These instruments include drill guides, drill guide plugs, drill bits, tubular chisels, trephines, tamps, transfer tubes, bone block compressor, drill bit adapters and a sterilizing tray. All instruments are composed of stainless steel. The instruments range in diameter from 2.7 mm to 10 mm.

#### **F. Indications For Use**

The Acufex® MosaicPlasty™ Comprehensive System is indicated for arthroscopic (knee and ankle) and open osteochondral grafting for the treatment of osteochondral (cartilage) defects.

#### **G. Substantial Equivalence**

The components of the MosaicPlasty Comprehensive System are Class I exempt devices, except drill bits and adapters which are Class II. The components are similar in design, function, materials and intended use as other devices currently in commercial distribution. All devices are composed of stainless steel. The intended use and commercially available devices are presented in the table below.

Risks to health have been addressed through the specified materials, processing controls, quality assurance, and compliance to the Medical Device Good Manufacturing Practices regulations.

Intended Use	Current Product MosaicPlasty Comprehensive System Components	Substantially Equivalent Product
Drill Template	Drill Guide Arthroscopic Drill Guide	Drill Guide (Synthes®)
Use with Template	Drill Plugs Graft Template	Drill Sleeves (Synthes)
Drilling in Bone	2.4 mm Pilot Drill Bit 2.7 mm Arthr. Drill Arthr. Reamer Drills Drill Bits	Drill Bits (Synthes)
Harvesting Bone Grafts	Tubular Chisels	Gouges (Synthes)
Cutting circular bone section	Trephines	Trephine Drills (Smith & Nephew Endoscopy)
Tamping Graft into site	Tamps Transfer Plunger Sculpture Stick	Tamps (Zimmer®)
Transferring bone graft to recipient site	Transfer Tubes Arthr. Transfer Tubes Chisel Collar	Bone Graftor (Instrument Makar®)

Adapting drill bit or trephine to orthopedic drill	Trephine Adapters (Quick Coupling, Power)	Quick Coupling Adapter (Synthes)
Compress bone block	Bone Plug Compressor	Bone Compression Forceps (KMedic®)
For instrument access into joint	Metal Cannula	Metal Cannula (Smith & Nephew Endoscopy)

Applicant Tedd Loren Date 12/17/96